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(60) **References to other related national documents:**

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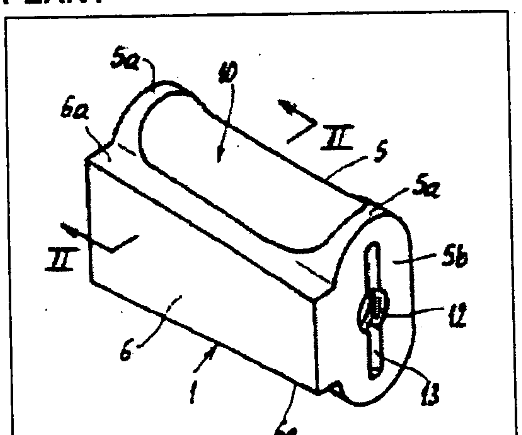
(54) INTERSOMATIC FRAME TYPE INTERVERTEBRAL IMPLANT

(57) According to the invention, this implant (1) consists of:
- a hollow body (5) that receives a bone graft, and whose upper and lower surfaces (5a) are designed to come into contact with the cancellous bone of the vertebral end plates (3a) and which have a contour that is of curvilinear transverse cross-section, and
- at least one lateral projection (6) that projects beyond the cavity (15) that accepts body (5) of implant (1) and which is designed to be inserted between the vertebral end plates (3a), at the level of unresected surfaces that consist of subchondral hard bone.



The present invention involves an intervertebral implant, of the type typically referred to as "intersomatic scaffold", and which allows immobilization of two adjacent vertebrae. It also involves three related instruments for implantation of this implant.

Degeneration of an intervertebral disk leads to local compression of the spinal cord and nerve roots. This makes it necessary to restore the intervertebral space and to immobilize the vertebrae located on either side of the affected disk.

One technique consists of implanting a bony graft between the two vertebral plates, after ablation of the disk. One such graft slightly resists the stresses exerted by the patient's movements, and poses a risk of shifting itself lengthwise along one or the other of the vertebrae.

A concept has therefore been proposed that places the graft inside a rigid implant, or "intersomatic scaffold", which is open at its upper and lower ends. This type of implant has a greater height than that of the intervertebral space to be restored, such that it is necessary, during preparation of the site, to dig out the hard sub-chondral bone in the vertebral plates until the cancellous bone is reached. After implantation, the graft comes into contact with this cancellous bone and "osteo-integration" can then take place.

Some scaffolds are generally cylindrical or tapered in shape. They have the advantage of being relatively easy to implant, because the recess into which they will be fitted can be easily shaped just by drilling. Moreover, their rounded shape allows a significant contact surface to be achieved between the graft and the cancellous bone of the vertebrae, and a compression of the graft results that encourages fusion.

These scaffolds nevertheless have the drawback of presenting non-negligible risks of insertion in one or the other of the vertebrae. In effect, they rest primarily on the cancellous bone and their round shape promotes this insertion.

It is of course possible to reduce the dimensions of the upper and lower openings of the scaffold, in order to increase the support surface against the bone, but this reduction takes place to the detriment of the contact surface between the graft and the bone, and therefore to the detriment of the solidity of the fusion.

Other scaffolds are parallelepipedal in shape.

They pose less risk of intrusion than cylindrical scaffolds, thanks to their flat support surfaces, and are shorter than cylindrical scaffolds, which requires less ablation of the sub-chondral bone.

Even so, creating a recess of square or rectangular cross section involves drilling a bore, then a cutting out the four angles in the recess of the sub-chondral bone using a chisel punch. Handling this type of instrument, near the spinal cord and nerve roots, is extremely delicate.

The present invention is intended to remedy these various drawbacks.

The implant or "scaffold" involved comprises:

- a body that accepts a bony graft, and whose upper and lower sides are designed to come into contact with the cancellous bone of the vertebral plates and whose transverse cross-sections have a curvilinear contour, and
- at least one lateral projection whose height is largely the same as that of the intervertebral space to be restored, and where this protuberance projects beyond the cavity that is to accept the body

of the implant and which is designed to be inserted between the vertebral plates, at the level of plates' non-resected surfaces, which consist of hard sub-chondral bone.

The scaffold according to the invention allows good osteo-integration, thanks to the curvilinear shape of the upper and lower sides of the body that receives the graft, which ensures significant contact surfaces for the graft with the cancellous bone, and compression of the graft, without risk of intrusion in the cancellous bone, thanks to the rigid bracing that constitutes the lateral protuberance.

Eliminating the risk of intrusion allows provision of upper and lower openings of maximum dimension, which ensures solid and rapid fusion.

Providing a receptacle for inserting the scaffold involves drilling a bore through the affected disk and a part of the sub-chondral bone in the vertebral plates, according to standard procedure, which is relatively easy to do, and providing, on one of the lateral sides of this bore, a groove designed to receive the lateral protuberance. Providing this groove, solely through the disk, is also an operation that is relatively easy to carry out.

Preferably, the scaffold is shaped so that its protuberance is located, when it is implanted, on the outer side of the vertebrae, relative to the axis of the spine, and therefore far from the spinal cord and the nerve centers. All risk of lesion is thus reduced to a minimum.

The body of the scaffold may have a cross section that is circular in shape. Still, preferably, the transverse cross-section has an annular or oval shape, with the greatest dimension of this ring or oval placed vertically when the scaffold is implanted.

This annular or oval shape allows the scaffold to have, for a given height, a width that is less than that of a scaffold of circular cross section. The recess bored for the scaffold is thus kept at a distance from the spinal cord and nerve centers located along the axis of the spine.

The protuberance can have parallel support surfaces, in the case of a scaffold designed to be implanted between the vertebrae with largely parallel plates. The projection can also have support surfaces that are inclined so that they converge towards each other in the direction of the rear extremity of the scaffold. This type of scaffold is adapted to vertebrae whose plates are not parallel, and allows the vertebrae's anatomical curvature to be reestablished as it was before degradation of the disk.

The body of the scaffold can, moreover, have a constant transverse cross-section, specifically cylindrical, or a transverse cross-section that is decreased in the direction of the rear extremity of the scaffold. The body of the scaffold also participates in the reestablishment of the anatomical curvature of the vertebrae.

Moreover, the body can have a rear side that is inclined such that the lower surface of the body is increased. Such a scaffold can be implanted in cases of spondylolisthesis, and has a maximum support surface on the lower vertebra.

The scaffold according to the invention can be implanted through the front or the back, and comprises tapped bores located in the front and rear sides, so it can be mounted on the end of an instrument for introduction and impacting. Preferably these borings discharge into the cavity of the scaffold that receives the graft, in order to allow injection of cancellous bone chips into this cavity, using this instrument, which will be described later.

The invention also involves three ancillary instruments that are used for implantation of the scaffold.

The first of these instruments is a guide for drilling that consists of a tubular portion designed to guide a drill bit and two parallel blades at the free cutting end, which causes longitudinal projection of an end of this tubular part, on its two opposing sides; one of these blades has a height and a thickness that are largely the same as the maximum height and thickness of the scaffold's protuberance.

These blades are designed to be inserted into the disk, before drilling of the cavity into which the scaffold is to be implanted. They allow perfect immobilization of the drill guide relative to the disk and vertebrae. The blade whose height and thickness are largely the same as the maximum height and thickness of the lateral projection of the scaffold allow the placement, by simple insertion, of the groove designed to accept this protuberance. The second blade, for its part, allows us to ensure stability in rotation of the drilling guide.

The second of these ancillary instruments is an osteotome, which allows removal of the bony graft intended to fill the scaffold. This osteotome consists of a graft receptor cavity, bounded by a free slicing edge; this cavity has a shape that largely corresponds to the shape of the cavity in the scaffold. The graft removed thus precisely adapts to the cavity in the scaffold.

The third ancillary instrument is the abovementioned instrument used for impaction and insertion of the scaffold between the vertebrae. According to the invention, this instrument is tubular in shape and consists of a piston that can slide in its interior bore. It thus allows the user to inject cancellous bone chips

into the cavity in the scaffold that is to receive the graft, in such a way as to ensure perfect filling of this cavity.

For proper comprehension, the invention is once again described below with reference to the attached schematic drawings which show, purely as non-limiting examples, several variations of the embodiment of the intervertebral implant involved, as well as a shape of the embodiment of the various ancillary instruments for the implantation of this implant.

Figure 1 is a perspective view of the implant, according to a first manner of embodiment.

Figure 2 is a section view through line II-II in figure 1

Figure 3 is a side view, after implantation between two vertebrae.

Figure 4 is a rear view of two vertebrae after implantation of an implant on the right side and drilling, on the left side, of the recess intended to receive an implant.

Figure 5 is a view from above of these two implants, after installation.

Figure 6 is a perspective view of a first ancillary instrument that allows installation of this implant.

Figure 7 is an end view of this instrument during use.

Figure 8 is an end view of this instrument, according to one variation.

Figure 9 is a perspective view of a second instrument that allows removal of a bony graft.

Figure 10 is a section view through line X-X in figure 9.

Figure 11 is a longitudinal section view of a third ancillary instrument that allows installation of this implant, in its unmounted state.

Figure 12 is a partial view of this instrument during installation of an implant, in its first position.

Figure 13 is a view similar to that in figure 12, in the second position of the instrument

Figures 14 through 19 are views, similar to figure 1, of the implant according to several variations of embodiment, and

Figure 20 is a side view of the implant shown in figure 19, after implantation between two vertebrae, in the case of a spondylolisthesis.

Figures 1 and 2 represent, at different angles, an intervertebral implant 1, of the type popularly called "intersomatic scaffold".

As is shown in figures 3 through 5, two implants 1 are each designed to receive a bony graft 2 and to be inserted between two vertebrae 3 of which disk 4 is deteriorated. Implants 1 allow the intervertebral space to be restored and relative immobilization of vertebrae 3 to take place.

Frame 1 consists of a body 5 and a lateral projection 6.

Body 5 features a transverse cross-section of annular shape that bounds an interior receptor cavity 10 for graft 2. This cavity 10 discharges to the outside through two wide openings provided in the rounded longitudinal sides 5a in this body 5.

The two lateral sides in end 5b of body 5 each comprise a central tapped bore 12, and one of them has a transverse groove 13.

Projection 6 forms a single piece with body 5. It has the shape of a polyhedron bordering two longitudinal sides 6a, which converge towards each other

in the direction of one of sides 5b of body 5, symmetrically relative to a longitudinal median plane of projection 6.

It appears, on figures 3 and 4, that body 5 has a height that is greater than the intervertebral space to be restored. The provision of cavity 15 intended to accept this body 5 consequently implies drilling not only disk 4 but also the sub-chondral bone in vertebral plates 3a, until the cancellous bone is reached. Graft 2 can thus come into contact with this cancellous bone in order to allow osteo-integration to take place.

On the other hand, the height of protuberance 6 largely corresponds to the height of the intervertebral space to be restored, and this projection is designed to be captured in a groove 16 provided on the exterior side of cavity 15, which is present in disk 4 only. Projection 6 is thus inserted in the vertebral plates 3a, at the level of the non-resected surfaces of these plates, consisting of hard sub-chondral bone, where these plates 3a are supported against sides 6a.

Figure 6 shows a drill guide 20 that allows cavity 15 and groove 16 to be located. This drill guide 20 consists of a tubular part 21 that guides a drill bit and two parallel blades 22, 23 at the free slicing end. These blades 22, 23, project longitudinally from one of the ends of this tubular part 21, on the two opposing sides of this part.

Blade 22 has a height and thickness that largely correspond to the maximum height and thickness of projection 6.

Tubular part 21 is annular in shape and allows location of cavity 15, by drilling two offset parallel bores. As shown in figure 7, this tubular part 21 comprises two barrels 24 that are partially secant, for guiding the bit. Figure 8 shows that, according to one variation, this part 21 can

comprise an annular cavity and a removable longitudinal shim 25 in the shape of a half-moon, that allows each of the two boring cannons to be successively bounded.

Figures 9 and 10 show an osteotome 30 that allows removal of a bony graft 2. This osteotome 30 comprises, at one end, a striking head 31 and, at its other end, a receptor cavity 32 for the graft, bounded by a free slicing edge 33. This cavity 32 has a shape that is largely the same as the shape of cavity 10, such that graft 2 adapts precisely to this cavity.

Osteotomy 30 also consists of a cursor 35 that bounds the bottom of cavity 32, guided by a shaft 36 that slides in a bore 37, and can be activated with a locking knob 38. This cursor 35 allows easy injection of graft 2 outside cavity 32.

Figures 11 to 13 show an instrument 40 that allows introduction and impaction of scaffold 1 in the housing consisting of cavity 15 and groove 16.

This instrument 40 comprises a tubular body 41, a striking head 42 at one end and a threaded end 43 at its other end. This end 43 can be screwed into one or the other of bores 12 in scaffold 1, depending to whether the scaffold is implanted first through the front or rear access.

Moreover, instrument 40 comprises a shaft 45 that forms a piston that can slide inside interior bore 46 of body 41.

In practice, vertebrae 3 are retracted for boring of housings 15, 16, then insertion of scaffolds 1.

As shown in figure 7, the boring guide 20 is first of all impacted until complete insertion of blades 22 and 23 in disk 4. These blades 22 and 23, once they are inserted, perfectly immobilize the boring guide 20. Blade 22 allows provision of groove 16 by this

simple insertion, whereas blade 23 ensures stability in rotation of boring guide 20.

Osteotomy 30 allows removal of graft 2, notably from the iliac crest of the patient. Slicing edge 33 ensures that graft 2 will be cut out in the shape of cavity 10 during hammering of the striking head 31. The graft obtained is thus homogeneous, in a single block

Its transfer into cavity 10 is carried out easily and quickly using cursor 35.

After drilling the two bores that allow provision of cavity 15 and retraction of guide 20, scaffold 1 is mounted on end 43 of instrument 40, then impacted inside recess 15 and 16. Once it is in place, an injection of cancellous bone chips into cavity 10 can be carried out by pressing on piston 45, as shown in figure 13, so as to ensure perfect filling of this cavity 10.

Groove 13 allows, in the case of defective positioning of scaffold 1 during impacting, this scaffold to be pivoted on itself in order to bring it to an adequate position.

It appears on figures 3 and 5 that the curved form of upper and lower sides 5a of body 5 allows significant contact surfaces of graft 2 with the cancellous bone, and compression of graft 2 which encourages vertebral fusion.

At the same time, risk of intrusion of scaffold 1 into the cancellous bone on one or the other of plates 3a is eliminated using protuberance 6, which consists of a rigid bracing on which these plates 3a are supported.

Elimination of the risk of insertion of scaffold 1 allows upper and lower openings to be provided for the scaffold, with maximum dimensions, which ensure solid and rapid fusion, and which are shaped in order to

allow, as shown in figure 3, lateral visualization, by fluoroscopy, of the graft-cancellous bone interface.

Moreover, convergence of surfaces 6a in the direction of the rear side of scaffold 1 allows this scaffold to reestablish the anatomical curve of vertebrae 3, that existed before degradation of disk 4.

Figures 14 to 19 show that numerous variations are possible in the shape of scaffold 1. By simplification, the elements already described in reference to figures 1 and 2, which are found in these variants, are designated by the same numerical references.

In general, body 5 can have a transverse cross-section of circular (figures 15, 18 and 19), annular (figures 14, 16 and 17) or oval shape, with the greatest dimension of this ring or this oval placed vertically when scaffold 1 is implanted.

Body 5 can also have a constant transverse cross-section (figures 14, 15, 19) or a transverse cross-section that decreases in the direction of the rear extremity of scaffold 1 (figures 16, 17, 18), in order for body 5 to participate, along with protuberance 6, in the reestablishment of the anatomical curve of vertebrae 3.

As for protuberance 6, it can have support surfaces 6a that converge in the direction of the rear extremity of scaffold 1 (figures 17, 18, 19) according to angles that can vary from 1 to 15 degrees, or it can have parallel support surfaces 6a (figures 14, 15, 16) which allow implantation of the scaffold between the vertebrae with largely parallel plates.

Moreover, as shown in figure 19, body 5 can have a rear side 5b inclined so as to increase the lower surface of body 5. This type of scaffold can be implanted in case of spondylolisthesis, as shown in figure 20, and has a maximum support surface on lower vertebra 3.

CLAIMS

1 – Intervertebral implant, allowing immobilization of two adjacent vertebrae, and distinguished by the fact that it consists of:

- a body (5) that accepts a bony graft (2), whose upper and lower sides (5a) are designed to come into contact with the cancellous bone of the vertebral plates (3a) and which has a curvilinear contour in transverse cross-section, and

- at least one lateral protuberance (6), whose height largely corresponds to that of the intervertebral space to be restored, and where this protuberance (6) projects beyond cavity (15) that is to receive body (5) of implant (1) and is designed to be inserted between the vertebral plates (3a) at the level of the non-resected surface consisting of the hard sub-chondral bone.

2 – implant according to claim 1, distinguished by the fact that it is shaped such that its protuberance (6), when it is installed in the spine, is placed on the exterior side of vertebrae (3) relative to the axis of the spine.

3 – Implant according to claim 1 or claim 2, distinguished by the fact that its body (5) has a transverse cross-section of circular shape, annular or oval, with the greatest dimension of this ring or this oval placed vertically when the implant (1) is affixed to the spine.

4 – Implant according to one of claims 1 through 3, distinguished by the fact that its protuberance (6) has support surfaces (6a) that are parallel or inclined so that they converge towards each other in the direction of the rear extremity of implant (1).

5 – Implant according to one of claims 1 through 4, distinguished by the fact that its body (5) has a constant transverse cross-section, specifically cylindrical, or a

transverse cross-section that decreases in the direction of the rear extremity of implant (1).

6 – Implant according to one of claims 1 through 5, distinguished by the fact that body 95) has a rear side (5b) that is inclined so that the lower surface of body (5) is increased.

7 – Implant according to one of claims 1 through 6, distinguished by the fact that it comprises bores (12) arranged in its rear and front sides (5b), these bores (12) discharge into cavity (10) that accepts graft (2).

8 – Implant according to one of claims 1 through 7, distinguished by the fact that these upper and lower openings are shaped so as to allow lateral visualization by fluoroscopy of the interface between the graft and the cancellous bone.

9 – Drill guide for locating the receptor housing (15, 16) of the implant according to one of claims 1 through 8, distinguished by the fact that it comprises a tubular part (21) that guides a drill bit and two parallel blades (22, 23) at the free cutting end that projects longitudinally from one end of this tubular part (21), on the two opposing sides of this part, where one of these blades (22) has a height and thickness that largely correspond to the maximum height and thickness of the protuberance (6) of implant (1).

10 – Osteotome that allows removal of graft (2) designed to fill implant (1) according to one of claims 1 through 8, distinguished by the fact that it consists of a graft receptor cavity (32), which is bordered by a free slicing edge (33), and where this cavity (32) has a shape that largely corresponds to the shape of cavity (10) in implant (1).

11 – Instrument that allows introduction, between the vertebrae and impaction of implant (1)

according to claim 7, distinguished by the fact that it is tubular in shape and that it comprises a shaft (45) that forms a piston, which can slide in an interior bore (46) of this instrument (40), in order to allow injection of cancellous bone chips into cavity (10) of implant (1).

FIG 1

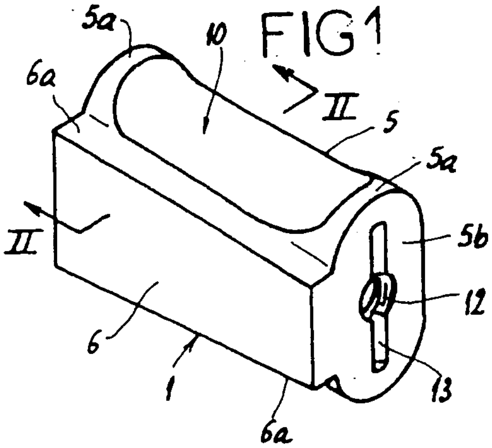


FIG 2

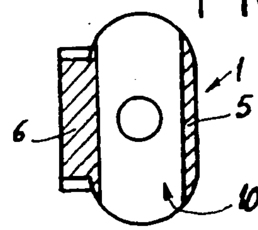
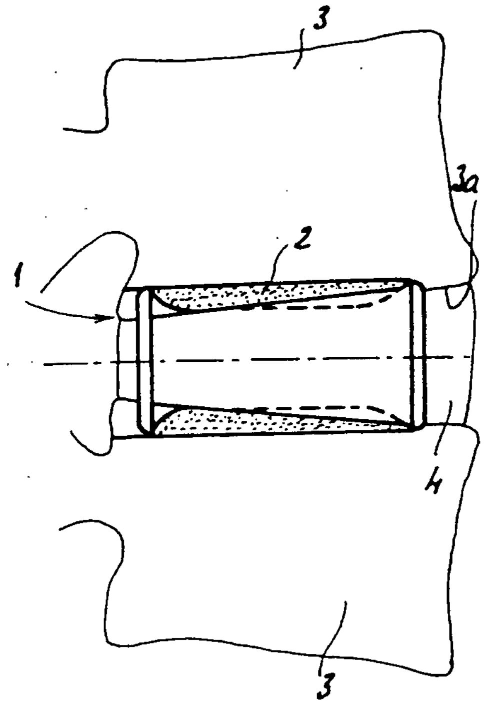


FIG 3



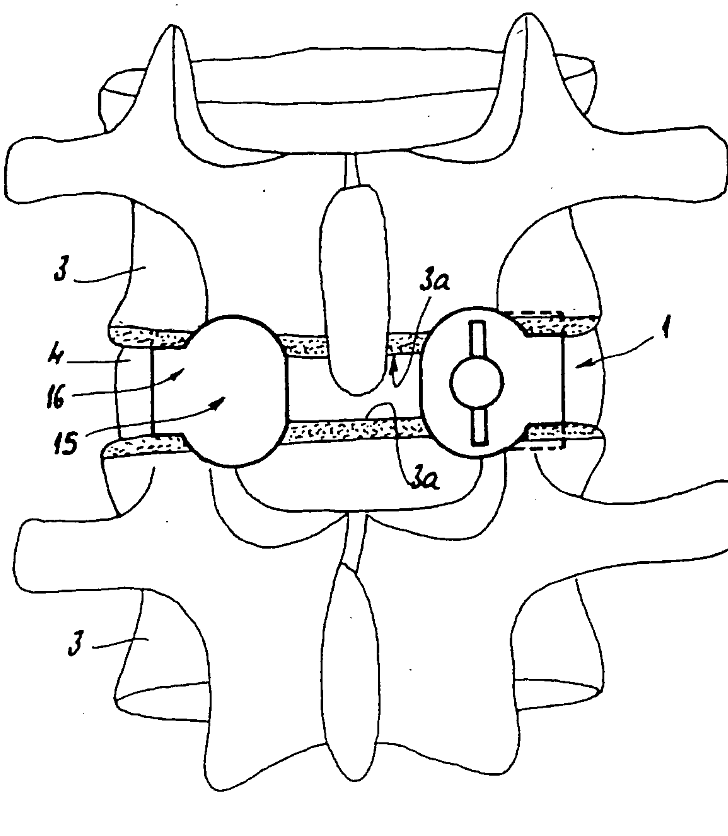


FIG 4

FIG 5

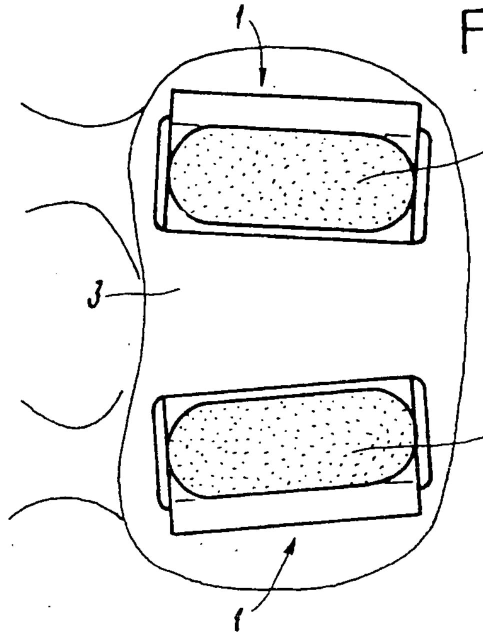


FIG6

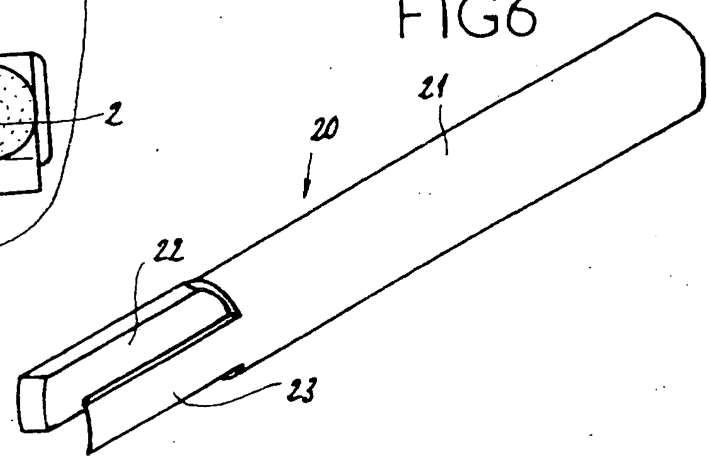


FIG 7

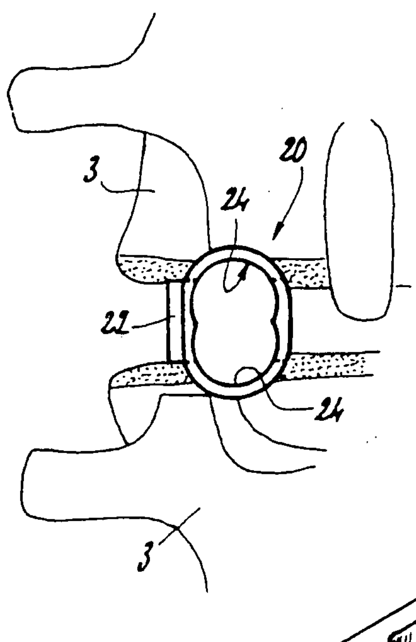


FIG 8

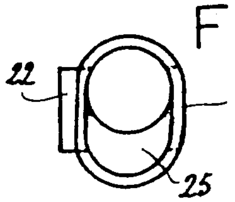
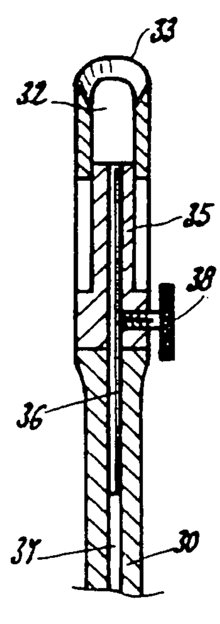


FIG 10



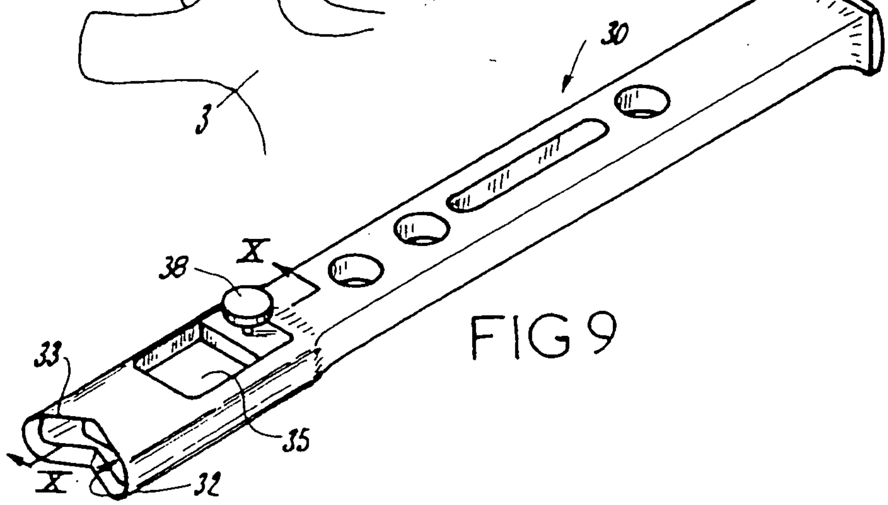


FIG 9

FIG 11

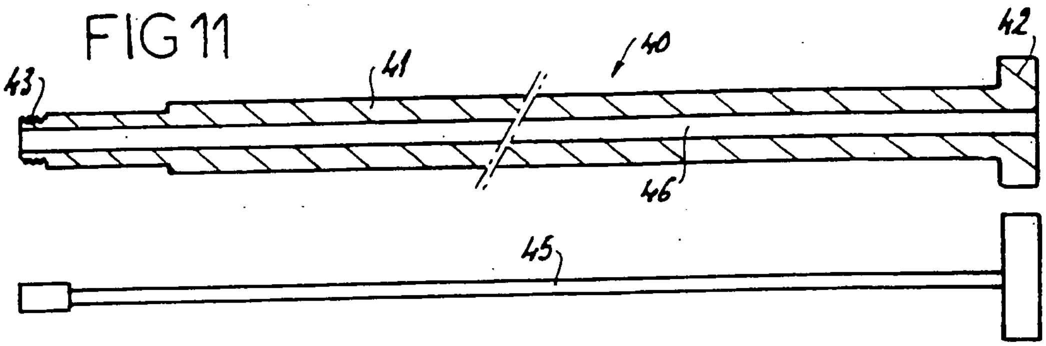


FIG 12

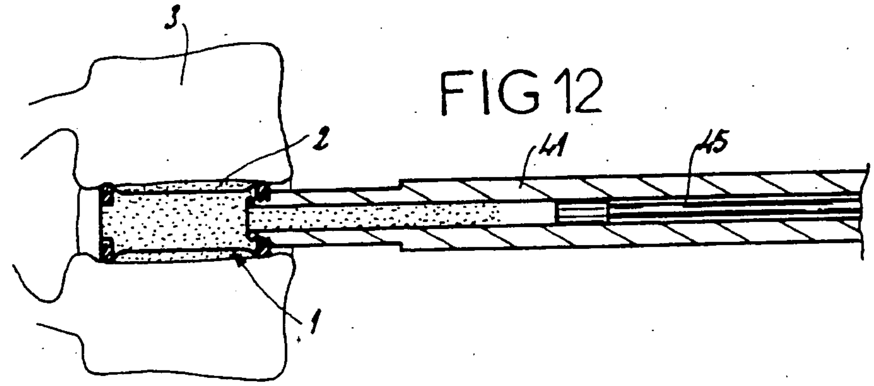


FIG 13

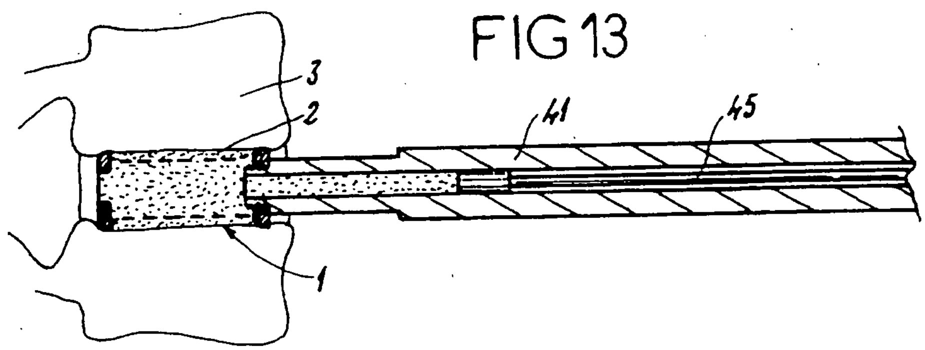


FIG 14

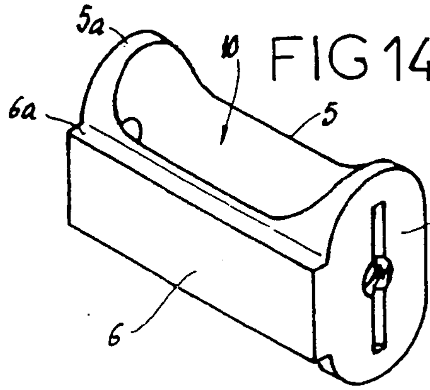


FIG 15

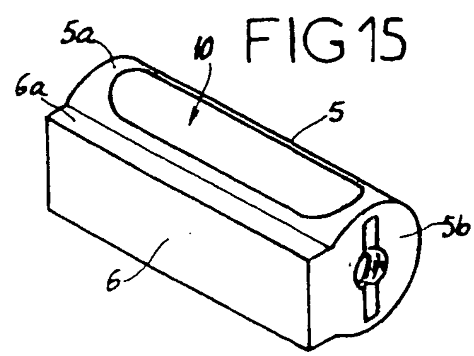


FIG 16

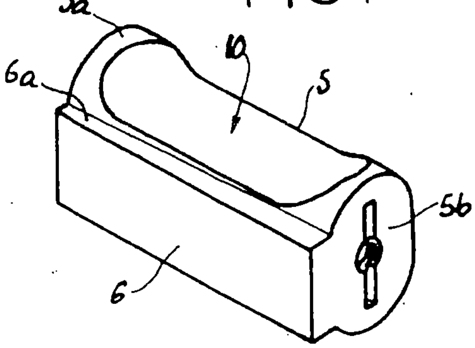


FIG 17

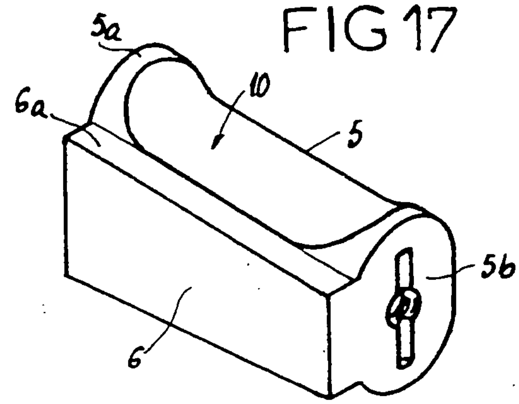
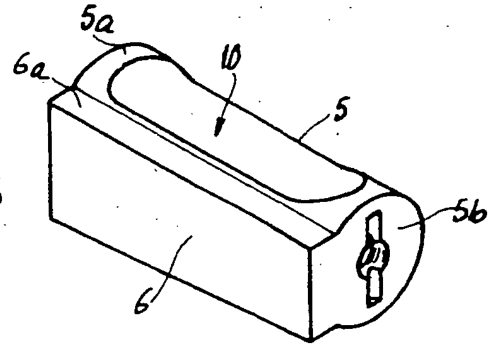


FIG 18



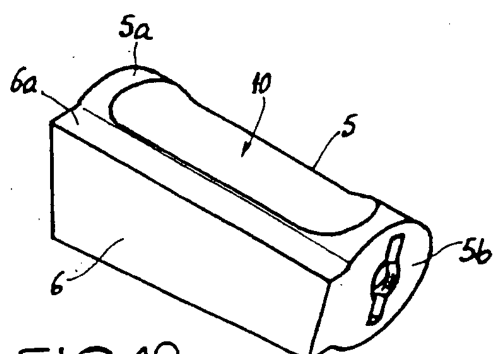


FIG 19

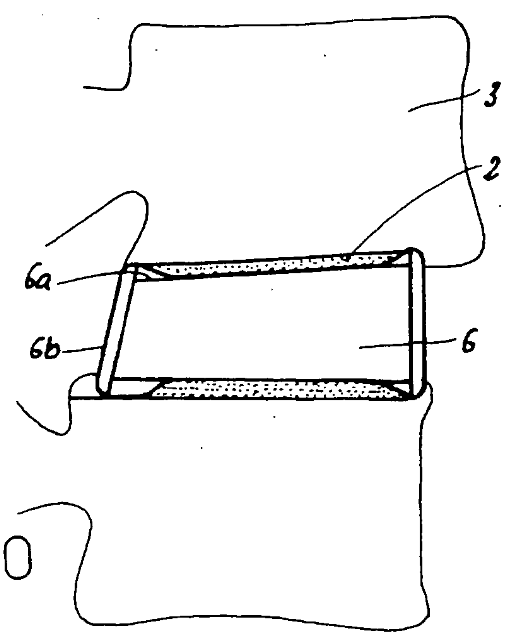


FIG 20